APR 19 2005

K050695

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	The Daavlin Distributing Company
Registration Number:	1526255
Address:	205 West Bement Street Bryan, Ohio 43506
Telephone:	419.636.6304
Contact:	David W. Swanson
Date Prepared:	March 4, 2005
Device Trade Name:	Flex Controlled Phototherapy Equipment
Device Common Name:	Ultraviolet Phototherapy Lamp
Device Classification:	Class II
Product Code:	FTC
Regulation Number:	CFR 878.4630
Regulation Name:	Ultraviolet lamp for dermatologic/skin disorders
Predicate Device:	Daavlin Distributing Company Spectra 300 Series, Ultraviolet Phototherapy Device, K828654 Spectra 724 Series, Ultraviolet Phototherapy Device, K854498 Spectra Mini Series, Ultraviolet Phototherapy Device, K820690

K051691

Device Description:

The Flex controlled phototherapy equipment is a microprocessor controlled fluorescent ultraviolet light source, with spectral output at peak wavelengths of 311 nm (Narrow Band UVB), 305 nm (Broad Band UVB) and 350 nm (UVA). It is intended for use by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema). The desired dose is selected using the operator interface located on the front panel of the device. The Flex controlled devices deliver full body phototherapy, whereby fluorescent tubes deliver the specified dose of UVA and/or UVB light.

Predicate Device Comparison:

The Flex controlled phototherapy equipment is constructed in the same design configuration as the predicate device, utilizing identical energy sources (UV lamps) and materials of identical composition. The Flex controlled devices vary from the predicate device, in that the control system hardware and software of the Flex control has been updated to utilize current technology. The intended use, general and specific indications for use, spectral output, mode of operation, labeling, treatment area, and general operating principals of the Flex controlled equipment are the same or similar to those of the predicate device.

Intended Use:

The Daavlin Flex controlled phototherapy equipment is a medical ultraviolet light source, which is intended for use for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I – VI).

Performance Data:

The Daavlin Flex controlled phototherapy equipment performance data is the same as or very similar to that of the claimed predicate device. The ultraviolet light tubes and cabinet construction used in the production of the predicate device and the Flex controlled phototherapy equipment are the same.

Conclusion:

On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the Flex controlled phototherapy equipment is substantially equivalent to the legally commercialized predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2005

Mr. David W. Swanson
Daavlin Distributing Co.
205 West Bement Street
Bryan, Ohio 43506

Re: K050695
Trade/Device Name: Flex Controlled Phototherapy Equipment
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: March 4, 2005
Received: March 18, 2005

Dear Mr. Swanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number K050695

Device Name Flex Controlled Phototherapy Equipment

Indications for Use

The Flex controlled phototherapy equipment is a medical ultraviolet device, which is intended for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I – VI).

Prescription Use _X_ OR Over-the-Counter Use ___

(per 21 CFR 801.109)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

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